UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	1:06-MD-1789-JFK **OPINION & ORDER**
This Document Relates to: Shirley Boles v. Merck & Co., Inc. Case No. 1:06-cv-09455-JFK	

APPEARANCES:

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JOHN F. KEENAN, United States District Judge:

This action was the first taken to trial in this multi-district products liability litigation concerning Defendant Merck Sharp & Dohme Corporation's ("Merck or "Defendant") prescription osteoporosis drug Fosamax. Following a lengthy trial, the jury could not reach a verdict and the Court declared a mistrial. Before the Court is Merck's post-trial motion for

judgment as a matter of law under Rule 50(b) of the Federal Rules of Civil Procedure. For the reasons that follow, the motion is granted in part.

I. BACKGROUND

Fosamax is an oral bisphosphonate manufactured by Merck for the treatment and prevention of osteoporosis.[1]

Plaintiff Shirley Boles ("Boles" or "Plaintiff") is a Florida resident who alleges that she developed osteonecrosis of the jaw ("ONJ") as a result of taking Fosamax for nearly eight years. She first was prescribed the drug in July 1997 by Dr. James Mills ("Dr. Mills"), a board-certified obstetrician and gynecologist. At that time, the T-score — a measure of bone mineral density — of Ms. Boles's hip was -2.1, meaning that the density of her hip bone was 2.1 standard deviations below that of an average female adult. There appears to have been several definitions of osteoporosis promulgated over time by different medical organizations, the precise boundaries of which are not relevant to the instant motion. At the time Dr. Mills prescribed Fosamax to Boles, the drug was indicated for use by patients with a T-score of -2.0 or worse.

[1] Additional information regarding Fosamax and its alleged link to ONJ can be found in the Court's ruling on the parties' Daubert motions. See In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164 (S.D.N.Y. 2009).

According to Plaintiff's medical records, she began having jaw complications following a tooth extraction in August 2002. Standard treatment methods were ineffective, and Plaintiff's condition persisted and gradually worsened. In late 2005, Plaintiff's medical records show that her condition deteriorated to the point where she had exposed necrotic bone in her jaw. Based on these records, Plaintiff's expert on causation, Dr. John Hellstein ("Dr. Hellstein"), testified that he believes that Plaintiff's use of Fosamax caused her to develop stage zero ONJ in August 2002, which eventually developed over time to become stage three ONJ.

Plaintiff began the trial with claims of strict product liability and negligence rooted in theories of failure to warn and design defect, and fraudulent misrepresentation and concealment.[2] Florida law governs these claims. Plaintiff's evidence at trial followed a few common themes. Plaintiff sought to prove that the benefits of Fosamax were overstated, in that certain reports and studies purportedly show that Fosamax (1) is ineffective in the first 18 months of use and again after 36 months of use, and (2) provides no benefit to patients, like Plaintiff, with a T-score better than -2.5. Plaintiff also

[2] In her Complaint, Plaintiff also alleged a breach of express and implied warranties. Those claims were withdrawn by Plaintiff prior to the Court's order on Merck's motion for summary judgment.

attempted to prove that Merck had long known, but failed to warn, of studies and reports linking bisphosphonate use with the development of ONJ.

Merck twice moved for judgment as a matter of law during trial pursuant to Rule 50(a): on August 21, 2009, at the close of Plaintiff's case, and on August 31, 2009, after both sides rested. The Court dismissed the fraudulent misrepresentation and concealment claims after the close of evidence, finding that a reasonable jury could not find that Merck intentionally misrepresented or concealed the risk of ONJ before the date of Plaintiff's injury. (Trial Tr. at 2359-60.) Merck's motion for judgment as a matter of law was denied with respect to Plaintiff's other claims. The jury informed the Court after several days of deliberation that it was deadlocked and could not reach a verdict on any of Plaintiff's remaining claims. As a result, the Court declared a mistrial on September 11, 2009.

II. DISCUSSION

Merck timely filed the instant motion on September 25, 2009. It contends that it is entitled to judgment as a matter of law because Plaintiff failed to introduce evidence on critical elements of her strict liability and negligence claims. Specifically, Merck argues that (1) all of Plaintiff's claims fail because she has not submitted evidence to show she developed ONJ prior to October 1, 2003; (2) it is entitled to

judgment as a matter of law on Plaintiff's failure to warn claims because, among other things, there was no evidence introduced at trial to support proximate causation; and (3) no reasonable jury could have found for Plaintiff on her design defect claims because there was no evidence at trial that Fosamax is unreasonably dangerous or that Merck breached any duty of care as to render it liable under Plaintiff's negligent design claim.

A. Rule 50

"Under Rule 50(a), a party may move for judgment as a matter of law during trial at any time prior to the submission of the case to the jury." Galdieri-Ambrosini v. Nat'l Realty & Dev. Corp., 136 F.3d 276, 286 (2d Cir. 1998); see Fed. R. Civ. P. 50(a). Under Rule 50(b), if the Court does not grant the Rule 50(a) motion at the close of evidence, the moving party may renew its motion for judgment as a matter of law under Rule 50(b) within 10 days[3] of an unfavorable judgment — or, as here, the order of a mistrial — but it "is limited to those grounds that were specifically raised in the prior [Rule 50(a) motion]." Galdieri-Ambrosini, 136 F.3d at 286; see Fed. R. Civ. P. 50(b).

[3] Rule 50(b) recently was amended, effective December 1, 2009, to extend the filing deadline to 28 days after the entry of judgment. The instant motion was submitted before the amendment came into effect.

The movant faces a "high bar," Lavin-McEleney v. Marist Coll., 239 F.3d 476, 479 (2d Cir. 2001); motions for judgment as a matter of law "should be granted cautiously and sparingly." Meloff v. N.Y. Life Ins. Co., 240 F.3d 138, 145 (2d Cir. 2001). In deciding the motion, the Court "must view the evidence in a light most favorable to the non-movant and grant that party every reasonable inference that the jury might have drawn in its favor." Merrill Lynch Interfunding, Inc. v. Argenti, 155 F.3d 113, 120-21 (2d Cir. 1998) (quoting Samuels v. Air Transport Local 504, 992 F.2d 12, 14 (2d Cir. 1993)). The Court "may not itself weigh the credibility of witnesses or consider the weight of the evidence." Galdieri-Ambrosini, 136 F.3d at 286. The Court may properly grant such a motion only where it "finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for" the non-movant. Fed. R. Civ. P. 50(a); see Arlio v. Lively, 474 F.3d 46, 51 (2d Cir. 2007) (holding that judgment as a matter of law should be granted when "the evidence, viewed in the light most favorable to the nonmoving party is insufficient to permit a reasonable juror to find in [the non-moving party's] favor").

B. Timing of Plaintiff's Injury

Merck contends that Plaintiff's negligence and strict liability claims fail as a matter of law because she did not establish that she developed ONJ prior to October 1, 2003. The

importance of that date derives from the Court's decision to grant in part Merck's motion for summary judgment. The Court found that, with regard to the date that Plaintiff first developed her injury, Plaintiff alleged in opposition of Merck's motion for summary judgment "one set of facts in support of her failure to warn claims and then allege[d] a conflicting set of facts in order to admit an expert to support those claims and to demand punitive damages flowing from those claims." In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 276 (S.D.N.Y. 2009). The Court, therefore, construed Plaintiff's statements as a judicial admission that she developed ONJ by no later than September 2003 and granted Merck's motion to the extent Plaintiff's claims are predicated on her developing ONJ later than September 2003. Id. at 276, 285.

Even if Merck is correct that the lack of such evidence is an appropriate basis for the Court to dismiss all of Plaintiff's claims, its motion is denied with respect to this issue because a reasonable jury could find that Plaintiff developed her injury before October 2003. Plaintiff's medical records indicate that her jaw problems have been fairly continuous since August 2002, when she first began having jaw complications following a tooth extraction. Records from August 2002 indicate that Plaintiff had an ulcer and swelling in the area of extraction, which also generally evidenced delayed healing. (Trial Tr. at 630.) Dr.

Hellstein explained that findings in a pathology report from the same month indicate that she had dead bone in her jaw. (Id. at 633-36.) Also, a radiograph taken before October 2003 showed her jaw as having a "moth-eaten" appearance, which is consistent with necrosis. (Id. at 739.) Based on her records, Dr. Hellstein opined that Plaintiff's jaw injury began as stage zero ONJ in August 2002 and progressively worsened to stage three ONJ. (Id. at 625-26, 735.)

Accordingly, Merck's motion for judgment as a matter of law is denied with respect to this timing issue.

C. Failure to Warn

Under Florida law, manufacturers of drugs have a duty to provide adequate warnings of dangerous side effects. Upjohn Co. v. MacMurdo, 562 So. 2d 680, 683 (Fla. 1990); Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981). "Florida courts impose different standards in assessing liability under negligence and strict products liability," Jennings v. BIC Corp., 181 F.3d 1250, 1256 (11th Cir. 1999), yet under a failure to warn theory each essentially "boil down to three elements that Plaintiff must prove: 1) that the warnings accompanying the item were inadequate; 2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and 3) that Plaintiff in fact suffered an injury by using the product."

Colville v. Pharmacia & Upjohn Co. LLC, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008).

"One method of negating proximate cause is for the defendant to demonstrate that even an adequate warning would not have altered the particular plaintiff's course of conduct." Stanley Indus., Inc. v. W.M. Barr & Co., 784 F. Supp. 1570, 1574 (S.D. Fla. 1992). Under the "learned intermediary doctrine," a prescription drug manufacturer's duty is to warn the physician rather than the patient. See Buckner, 400 So. 2d at 822. It is then the prescribing physician's task to inform himself of the qualities and risks associated with the products he prescribes, and to make an independent judgment of the best course of treatment, "taking into account his knowledge of the patient as well as the product." Id. at 823 (quotation omitted). Therefore, in the prescription drug context, it is the prescribing physician's hypothetical course of conduct had an adequate warning been given that is most relevant to the issue of proximate cause.

Merck contends that Plaintiff cannot establish proximate causation on her failure to warn claims, arguing that she has introduced no evidence that her treating physician would have heeded a warning regarding the risk of ONJ. The Court previously denied Merck's motion for summary judgment on this very issue, finding that there was sufficient record evidence

for a reasonable jury to find that the failure to warn of the risk of ONJ proximately caused Plaintiff's injury. See In re Fosamax, 647 F. Supp. 2d at 282. The Court specifically pointed to the affidavit of Plaintiff's prescribing physician, Dr. Mills, in which he stated that he received no warning that the suppression of bone turnover — which is considered a plausible explanation for how Fosamax may cause ONJ — could have clinically significant adverse event outcomes. His affidavit further provided that had he known of these adverse event outcomes, he likely would have changed his course of treatment. Based on this evidence, the Court denied Merck's motion for summary judgment.

Dr. Mills's testimony at trial differed from his affidavit in an important manner. At trial, Dr. Mills testified that he would not have prescribed Fosamax to Plaintiff had he known the complete truth regarding Fosamax's efficacy. He explained that he believes Plaintiff, who had a T-score of -2.1 at the time he prescribed her Fosamax, received no benefit from the drug based on reports and studies that evidence that Fosamax has no fracture reduction efficacy in patients with T-scores better than -2.5. Based on the lack of perceived benefit, he would not have prescribed her Fosamax, reasoning concisely: "[I]t wouldn't have done any good. And it's expensive." (Trial Tr. at 487.) Dr. Mills also added that he probably would not have

prescribed Fosamax to Plaintiff had he known that generally it is only effective for patients for an eighteen-month period of use. He reasoned that he would not advise a patient to take a drug for four years to yield only eighteen months of benefit. (Id. at 492.) Dr. Mills also testified generally regarding Plaintiff's jaw condition, including her symptoms and their effect on her well-being, but did not comment on the manner in which he would have treated Plaintiff had he known of the risk of developing ONJ, setting aside all alleged previously undisclosed information regarding Fosamax's efficacy.

According to Plaintiff, she established proximate causation in that Dr. Mills's testimony shows that had he known the "whole truth" regarding Fosamax — of both its risks and efficacy — then he would not have prescribed her Fosamax. It would be a logical fallacy to consider Dr. Mills's testimony evidence with which a reasonable jury could conclude that Merck's alleged failure to warn of ONJ was a proximate cause of Plaintiff's injury. Based on his testimony, if he had known of this newly-acquired information regarding Fosamax's efficacy at the time he prescribed it to Boles, he would haven taken a different course of treatment regardless of whether Merck adequately warned him of the risk of ONJ or any other potential side-effect. Plaintiff essentially concedes as much, stating in her opposition brief that based on Dr. Mills's interpretation of

this newly-acquired information, "any potential risk, be it a risk of harm Ms. Boles suffered or not, outweighs the complete lack of any benefit." (Pl. Opp'n at 11.) This evidence only tends to show that Dr. Mills would have changed his course of conduct had he known the "whole truth" regarding the efficacy of Fosamax, and so it is this alleged failure to disclose the truth regarding Fosamax's efficacy that is a proximate cause of Plaintiff's injury.

Plaintiff cannot save her claim by recasting it as one seeking relief for a failure to warn of both the risks and limitations of the efficacy of Fosamax. As an initial matter, Plaintiff pleaded her failure to warn claim based solely on Merck's alleged failure to warn of the risks associated with Fosamax, specifically ONJ. See, e.g., Compl. ¶ 47 (alleging that Merck failed to exercise due care by selling Fosamax "without an adequate warning of the significant and dangerous risks"); Compl. ¶ 57 (alleging that Merck should be held strictly liable in that it did not provide "warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw"). She cannot recharacterize her claim during trial in an effort to overcome the lack of evidence with regard to proximate cause.

Moreover, plaintiffs alleging a failure to warn under Florida law must establish that the inadequate warning was in regard to a risk or danger associated with the product. See, e.g., Pinchinat v. Graco Children's Prods., Inc., 390 F. Supp. 2d 1141, 1146 (M.D. Fla. 2005) ("[P]laintiff must prove that defendant . . . did not adequately warn of a particular risk."); Zanzuri v. G.D. Searle & Co., 748 F. Supp. 1511, 1516 (S.D. Fla. 1990) ("[A] drug manufacturer will not be held liable in Florida where it can show that it provided the medical community with an adequate warning of the risks associated with the product."); Scheman-Gonzalez v. Saber Mfg. Co., 816 So.2d 1133, 1139 (Fla. Dist. Ct. App. 2002) ("[T]o warn adequately, the product label must make apparent the potential harmful consequences."); Cohen v. Gen. Motors Corp., 427 So. 2d 389, 390 (Fla. Dist. Ct. App. 1983) ("[A] warning of a known danger in a non-defective machine is required in the exercise of reasonable care." (quoting Am. Cynamid Co. v. Roy, 466 So. 2d 1079, 1082 (Fla. Dist. Ct. App. 1984))). To allow Plaintiff to pursue a claim for the "failure to warn" of the efficacy of a drug would be an expansion of liability under Florida law.

In sum, contrary to Plaintiff's interpretation of Florida law, Plaintiff cannot establish proximate cause without evidence that Merck's failure to warn of the specific risk that allegedly materialized to cause Plaintiff's injury affected her treating

physician's course of treatment. The trial was completely devoid of such evidence and therefore Plaintiff's failure to warn claims fail as a matter of law. Plaintiff's motion is granted with respect to the failure to warn claims.

D. Design Claims

"Under Florida law, a strict product liability action based upon design defect requires the plaintiff to prove that (1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5) injury." See Pinchinat, 390 F. Supp. 2d at 1148. "[I]t is unnecessary in a strict liability action to show that the manufacturer has been negligent in any way. In fact [it] can be found liable even though [it] was utterly non-negligent." Moorman v. Am. Safety Equip., 594 So. 2d 795, 800 (Fla. Dist. Ct. App. 1992).

The basic elements of Plaintiff's negligence claim are well-established: (1) a legal duty on the part of the defendant towards the plaintiff under the circumstances; (2) a breach of that duty by the defendant; (3) the defendant's breach of duty was both the actual and proximate cause of the plaintiff's injuries; and (4) the defendant suffered damages as a result of the breach." Pinchinat, 390 F. Supp. 2d at 1148. A plaintiff alleging negligent design also must show that the product was unreasonably dangerous. See Marzullo v. Crosman Corp., 289 F.

Supp. 2d 1337, 1342 (M.D. Fla. 2003) (holding that a plaintiff alleging negligent design "also must establish that the product was defective or unreasonably dangerous); Terex Corp. v. Bell, 689 So. 2d 1122, 1123 (Fla. Dist. Ct. App. 1997) ("Because the only evidence of negligence offered against appellant at trial related to its alleged negligent design and the jury found there was no design defect, there was no evidence to sustain its verdict.").

Judgment as a matter of law would be appropriate on both Plaintiff's strict liability design defect claim and negligent design claim if, as Merck contends, Plaintiff failed to introduce evidence that Fosamax is unreasonably dangerous. A product is unreasonably dangerous if "the risk of danger in the design outweighs the benefits." Florida Standard Jury Instructions in Civil Cases § PL 5.[4] There is a rebuttable

[4] Plaintiff contends that under Florida law the Court should apply the "consumer expectation test" in determining whether a product is unreasonably dangerous. Florida courts have applied this test on a few occasions. Under the consumer expectation test, "a product is defectively designed if the plaintiff is able to demonstrate that the product did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner." Force v. Ford Motor Corp., 879 So. 2d 103, 106 (Fla. Dist. Ct. App. 2004). The court in Force also observed, though, that "there may . . . be products that are too complex for a logical application of the consumer-expectation standard." Id. at 110; see also Tran v. Toyota Motor Corp., 420 F.3d 1310, 1314 (11th Cir. 2005) (holding that the consumer expectation test is not necessarily the proper test for all products liability cases, but is appropriate "when the product in question is one about which an ordinary consumer

presumption that a product is not defective or unreasonably dangerous, if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm complied with required statutes and regulations relevant to, and designated to prevent, the type of harm that allegedly occurred. Fla. Stat. Ann. § 768.1256 (2009). "The defectiveness of a design is determined based on an objective standard, not from the viewpoint of any specific user." Jennings, 181 F.3d at 1255.

With regard to risks, Plaintiff introduced the testimony of several expert witnesses who opined that Fosamax can cause ONJ. Merck contends, though, that Plaintiff cannot show that the risk of ONJ outweighs the drug's benefits. It cites to the trial testimony of Plaintiff's experts who acknowledged on cross-examination that "bisphosphonates are useful in [the] armamentarium of treating bone diseases" (testimony of Dr. Alastair Goss, Trial Tr. at 178-81); that Fosamax is a "good product" (testimony of Dr. Curt Furberg, Id. at 955); and that

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could form expectations"). This Court declined to instruct the jury that it could find Fosamax unreasonably dangerous under the consumer expectation test, and it again declines to apply it on this post-trial motion. Not only are prescription pharmaceuticals too complex for the straight-forward application of the consumer expectation test, the Florida District Court of Appeals recently held broadly that it is "inappropriate" for determining defectiveness. See Agrofollajes, S.A. v. E.I. Du Pont De Nemours & Co., Nos. 3D07-2322, 3D07-2318, 3D07-1036, 2009 WL 4828975, at *21 (Fla. Dist. Ct. App. Dec. 16, 2009).

the studies submitted for Fosamax's approval "were good studies that showed efficacy." (testimony of Dr. Curt Furberg, Id. at 1053.) These concessions are not fatal to Plaintiff's claim because Merck omits that with each of these statements, the witness was referring to benefits of Fosamax in treating osteoporosis, defined by each witness as patients with a T-score of -2.5 or worse. Under the standard used by these experts, Plaintiff only had osteopenia – lower than normal bone density that is not low enough to be classified as osteoporosis – and was prescribed Fosamax to prevent osteoporosis. On re-direct, Dr. Furberg testified at length regarding the lack of efficacy evidence for women with a T-score better than -2.5, i.e., those, like Plaintiff, that do not have osteoporosis. (Trial Tr. at 1028-30.) Dr. Suzanne Parisian ("Dr. Parisian"), Plaintiff's expert on FDA regulations for pharmaceuticals, also testified regarding studies that evidence the lack of efficacy data in preventing fractures for women with T-scores better than -2.5. (Id. at 1096-97, 1236-37.) Even if the jury finds that Merck has the benefit of a rebuttable presumption by way of Fosamax's FDA approval, based on this evidence, the jury may reasonably conclude that the risks of Fosamax outweigh its benefits when used for the prevention of osteoporosis by those with a T-score better than -2.5.

Plaintiff also introduced evidence from which a jury could find that Merck was negligent. Merck's arguments to the contrary are unavailing. For example, Dr. Parisian testified at length regarding a drug manufacturer's duty of pharmacovigilance under federal regulations, and instances in which she believes Merck fell short of those standards by failing to investigate reports of adverse events involving oral injuries and reports of Fosamax's inefficacy for osteopenic patients. (Id. at 1116-29, 1231-32.) Also, through the testimony of Merck employees responsible for pharmacovigilance, the jury could reasonably conclude that Merck did not properly conduct safety surveillance of Fosamax or have adequate procedures in place to review safety signals. (Id. 777-93, 810-11.). This testimony provides a sufficient evidentiary basis for a reasonable jury to find for Plaintiff on the negligent design claim.

Accordingly, Merck's motion is denied with respect to Plaintiff's design claims.

III. Conclusion

Merck's motion for judgment as a matter of law is granted in part, and denied in part. Plaintiff failed to introduce evidence at trial to support proximate causation on her failure to warn claims, and therefore those claims are dismissed. Plaintiff presented sufficient evidence for a reasonable jury to find in her favor on the design defect claims.

SO ORDERED.

Dated: New York, N.Y.
March 26, 2010

JOHN F. KEENAN
United States District Judge